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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,581	02/22/2001	Paolo Mascagni	205,042	9301
7590	02/08/2005		EXAMINER	
Abelman Frayne & Schwab 150 East 42nd Street New York, NY 10017-5612			MAIER, LEIGH C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/763,581	MASCAGNI ET AL.	
	<b>Examiner</b> Leigh C. Maier	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 September 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 15-26,28-35 and 38-52 is/are pending in the application.
- 4a) Of the above claim(s) 15-26 and 28 is/are withdrawn from consideration.
- 5) Claim(s) 29-35 and 38-44 is/are allowed.
- 6) Claim(s) 44-51,54 and 55 is/are rejected.
- 7) Claim(s) 52 and 53 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 29, 33, 41 and 42 have been amended. Claims 36 and 37 have been canceled.

Claims 45-52 have been newly added. Claims 15-26, 28-35, and 38-52 are pending. Claims 29-35 and 38-52 are under examination. Claims 15-26 and 28 were previously withdrawn as being drawn to a non-elected invention. Any rejection or objection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The declaration under 37 CFR 1.132 filed September 7, 2004 is sufficient to overcome the rejection of claims 29 and 32-44 based upon 35 USC § 102(b) by demonstrating that formation of an inclusion complex is not prepared by the process of RONSEN.

### ***Claim Rejections - 35 USC § 103***

Claims 45-51, 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over UEKAMA et al (US 5,904,929).

New claims 44-51, 54 and 55 are drawn to an inclusion complex of paroxetine and a CD derivative wherein the complex in the form of a flowing powder and is free of organic solvents. Dependents recite various salt forms, CD derivatives and component ratios.

UEKAMA teaches the preparation of clathrates of therapeutic agents and TV- $\beta$ -CD. See abstract; col 5, lines 22-26; col 6, lines 28-35; 7, lines 53-60; and examples 3-13. Example 13 illustrates an inclusion complex in the form of a powder that is pressed into a tablet for oral

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administration. The reference does not exemplify the use of paroxetine HCl, but its use is specifically suggested.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify any of the products disclosed in the examples by the substitution of paroxetine HCl or any salt. One of ordinary skill would reasonably expect success in making this modification because it was specifically suggested by the art. The artisan would be motivated to make this substitution for the art-disclosed utility of preparing a control-release product. It would be within the scope of the artisan to optimize the ratio of the components through routine experimentation.

***Allowable Subject Matter***

Claims 29-35 and 38-44 are allowed.

Claims 52 and 53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

As noted above, the declaration filed by Dr. Mascagni demonstrates that the Ronsen process does not inherently result in an inclusion complex, nor does it suggest any alteration to the process that might result in said complex.

Uekama suggests the preparation of a paroxetine complex with a per-acylated CD. The reference is limited to these CD derivatives and does not teach or fairly suggest the use of the CD derivatives recited in the claims.

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Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Examiner's hours, phone & fax numbers***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

*Leigh C. Maier*

Leigh C. Maier  
Primary Examiner  
February 7, 2005